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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,835	11/04/2003	Nicholas R. Bachur JR.	44995	5572

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EXAMINER

BITAR, NANCY

ART UNIT PAPER NUMBER

2624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/699,835

Applicant(s)

BACHUR ET AL.

Examiner

Nancy Bitar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/04/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation at lines 14-15 of claim 1 and lines 15-16 of claim 7 of "diagnostic significance of the information on the test strip, with respect to the corresponding the position of the test strip with respect to the test strip reader" is unclear, and confusing what feature or element is being further defined by this claim language, so that the claim fails to clearly point out and distinctly claim applicant's invention. Claims 2-6 are variously dependent from claim 1 and claims 8-13 are variously dependent from claim 7 and are thus similarly indefinite.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll et al (US 2005/0019945) in view of Wu et al (U.S. Patent No. 6,765,555).

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As to claim 1, Groll et al teaches a test strip reader comprising (biosensor for reading of the information by the test meter, paragraph [0009]):

an optical sensor with an imaging array of pixels (biosensor 401, paragraph [0058]);

a light source (laser light 412, paragraph [0058]);

a channel configured for receiving a test strip to be imaged by the test strip reader and for guiding the insertion and removal of the test strip with respect to the optical sensor (step 100, and 110, paragraph [0072]),

the test strip comprising optically detected information (information that can be encoded onto the test strip, [paragraph [0082]]);

a lens positioned with respect to the imaging array and the light source to focus light from the light source that has been reflected from the test strip onto the imaging array (The laser ablation process is performed by means of a laser which passes through a chrome-on-quartz mask. The mask pattern causes parts of the laser field to be reflected while allowing other parts of the field to pass through, creating a pattern on the gold which is ablated where contacted by the laser light, paragraph [0044]),

the optical sensor being operable to determine change of direction data corresponding to the position of the test strip with respect to the optical sensor (note that the positioning of the mask and movement ribbon and laser energy are computer controlled, paragraph [0061], and paragraph [0086]);

and a processing device connected to the optical sensor for using the change of direction data to determine the position of the test strip with respect to the test strip

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reader (each of the contact pads C, W, DC, and DW, as well as each of the contact pad positions B1-B7 are contacted by individual contacts of a multi-pin electrical connector located with the test meter when the test strip 300 is inserted in the test meter, paragraph [0086], and for determining at least one of the optical absorptions of the information on the test strip, and diagnostic significance of the information on the test strip, with respect to the corresponding the position of the test strip with respect to the test strip reader (paragraph [0086]; note that the quality of measurement result can be verified by allowing the meter to electronically assess the applicability of the ROM key data to the test strip inserted in the meter, paragraph [0070]).

While Groll et al. meets a number of the limitations of the claimed invention, as pointed out more fully above, Groll et al fails to specifically teach the imaging array of pixels.

Specifically, Wu et al. teaches the use of the sensor array 301 includes a plurality of individual pixels arranged in a two-dimensional array. In operation, as the optical mouse is pointed at any arbitrary image, the image is focused onto the sensor array 301 by lens 205 such that the sensor array 301 can obtain the raw image data. Because the optical mouse provides a movement vector (direction and motion) based on relative movement of successive images with respect to the sensor array. It would have been obvious to one of ordinary skill in the art to use the sensor array in Groll et al. in order to improve the quality and quantity of the data collection using the test strip and thus ensuring proper test result. . Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 2, Groll et al. teaches a test strip reader as claimed in claim 1, wherein the processing device is programmable to determine an average pixel value of at least part of a selected captured image by the imaging array (note that The test strip is mated to a nondisposable test meter such that the test meter can measure the reaction between the analyte of interest and the reagent in order to determine and display the concentration of the analyte to the user, paragraph [0005]) and to store the average pixel value (note that a common practice for downloading such calibration information into the test meter in the use of an electronic read-only memory key (ROM key) that is inserted into a socket of the test meter where the user confirm that the lot number of the test strip currently in use matches the lot number for which the ROM key was programmed, paragraph [0007]) with data relating to the corresponding position of the test strip with respect to the test strip reader when the captured image was captured (paragraph [0086]).

As to claim 3, Groll et al. teaches test strip reader as claimed in claim 2, wherein the processing device is programmable to generate and store a plurality of average pixel values with data relating to the respective positions of the test strip with respect to the test strip reader, and to locate indicia on the test strip using the stored average pixel values and the data (figure 9, the test meter compares (step 202) the lot ID of the calibration data stored within the ROM key currently inserted into the meter (or calibration data previously-loaded into the test meter internal memory) to the lot ID read from the test strip. If they do not match, the test meter displays the lot ID of the currently

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loaded calibration data (step 204) and a warning in order to give the user the chance to insert a correct test strip or to insert a different ROM key into the test meter; paragraph [0075], and paragraph [0076]).

As to claim 4, Groll et al. teaches test strip reader as claimed in claim 3, wherein the processing device is programmable to calculate the most likely target value of at least part of a selected captured image by the imaging array (figure 4, test strip for use in measuring the concentration of an analyte of interest in a biological fluid), and to store the most likely target value in a memory array mapped to the position of at least one of the indicia (the contact pad positions B1-B10 may be coded as a "0" or "1" in any possible ten digit digital word to be encoded onto the test strip. This provides 2^{sup}.10 or 1,024 possible unique words that can be encoded onto the test strip using the contact pad positions B1-B10 and stored in the ROM, it is noted a lot of features can be programmed in the test meter).

As to claim 5, Wu et al. teaches test strip reader as claimed in claim 1, wherein the optical sensor and the processing device are provided in an optical mouse engine (figure 2).

As to claim 6, Groll et al. teaches test strip reader as claimed in claim 1, wherein the processing device is programmable to determine if the test strip has been completely read by the optical sensor using data relating to the position of the test strip

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with respect to the test strip reader (note that if the test strip has not been completely read the test meter will display an error message to the user thus there is a record in the memory that the measurement result obtained is suspect in view of the discrepancy in the lot lds, paragraph [0076])

As to claims 7-13 differ from claims 1-6 only in that claims 7-13 are a method claims whereas, claims 1-6 are a system claim. Thus, claims 7-13 are analyzed as previously discussed with respect to claims 1-6 above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lee et al (US 6,392,632) is cited to teach an opt-electronic mechanism for capturing images and using image comparison to selectively provide cursor position signals based on the image comparison.

Suggs et al (US 5,729,361) Is cited to teach color image sensor device that uses LED and provide fine adjustment by scanning test strips that are read by a sensor using the varying LED power and exposure times.

Haar et al (US 6,880,968) Is cited to teach comprising test elements with a test zone, to be brought in contact with the sample to be investigated for the purpose of performing

an analysis, in order to measure a measurement quantity characteristic for the analysis, and an evaluation instrument with a test element holder for positioning a test element in a measuring position in order to perform a measurement, and a measurement and evaluation electronics for measuring the characteristic change and for determining a result of the analysis, based on the result of the measurement.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Bitar whose telephone number is 571-270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on 571-272-7695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nancy Bitar

01/18/2007



JINGGE WU
SUPERVISORY PATENT EXAMINER